

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BOARD OF PATENT APPEALS AND INTERFERENCES**

**APPEAL BRIEF**

**TITLE OF INVENTION:**

**SURGICAL CLIPS PARTICULARLY USEFUL IN THE  
ENDOLUMINAL TREATMENT OF GASTROESOPHAGEAL  
REFLUX DISEASE (GERD)**

Appl. No.: 10/010,246  
Applicant: Robert Sixto, Jr., et al.  
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Examiner: Darwin P. Erez  
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## **I. REAL PARTY IN INTEREST**

The real party in interest of the present application is Ethicon Endo-Surgery, Inc., the assignee of record, which is a subsidiary of the Johnson & Johnson Company. The present application was assigned to Ethicon Endo-Surgery, Inc., by an assignment dated January 8, 2007, which was recorded on January 11, 2007 (Reel/Frame No. 018763/0118).

## **II. RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

## **III. STATUS OF THE CLAIMS**

The status of each and every claim of the present application is as set forth herein. No claims have been allowed. Claims 1-10, 17, 18, and 21-32 are currently pending.

## **IV. STATUS OF AMENDMENTS**

On July 30, 2008, Appellants submitted a Preliminary Amendment amending claims 1, 17, 21, 22, and 32.

On July 7, 2009, Appellants submitted a Response with Amendment to the Final Office Action dated May 7, 2009.

The Examiner issued an Advisory Action on July 21, 2009, indicating that “the proposed amendment ... to recite that the ‘bridge connecting said first and second arms... retain the same initial shape prior to, throughout and subsequent to

application' changes the scope of the claimed invention and would require further consideration and an updated search" and did not enter the proposed amendments. The claims therefore stand as amended in the July 30, 2008 Preliminary Amendment.

Appellants filed a Pre-Appeal Brief on August 7, 2009. A Decision on the Pre-Appeal brief was issued on October 19, 2009.

**V. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 1, 2, 4, 17, 18, 21-23, 25 and 32 are currently rejected under 35 U.S.C. § 102(b) as being unpatentable by U.S. Patent No. 5,620,452 to Yoon.

Claims 3, 7, 24 and 28 are currently rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoon in view of U.S. Patent No. 5,222,961 to Nakao et al. (hereinafter "Nakao").

Claims 5, 6, 8-10, 26, 27 and 29-31 are currently rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoon in view of Nakao, and in further view of U.S. Patent No. 4,719,917 to Barrows et al. (hereinafter "Barrows").

**VI. SUMMARY OF CLAIMED SUBJECT MATTER/STATEMENT OF FACTS**

A concise explanation of the subject matter defined in each of the independent claims of the present application is as follows:

## A. Independent Claim 1

Independent claim 1 recites:

*A surgical clip, comprising:*

*a) a first arm;*

*b) a second arm substantially parallel to said first arm;*

*c) a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application;*

*d) at least one deformable retainer extending from one end of said arms in a direction, wherein*

*said retainer has a length in said direction of at least approximately  $\Pi$  times the distance between the arms when the arms are substantially parallel.*

As described in the specification of the instant application, the inventive surgical clip 310, shown in FIGS. 19 and 20, includes “two arms 312, 314 connected by a bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Application as originally filed*, page 25, lines 5-8.

“[W]hen the clip 310 is pushed forward, the retainer 320 is bent ... and the retainer 322 is bent ... to the configuration shown in Figure 20.” *Id.*, page 25, lines 14-17. It is only the retainer portions 320 and 322 of the clip that deforms. Compare FIG. 19 to FIG. 20. Both before, during, and after the bending process,

the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U-shape. *Id.* This static U-shape is shown in FIGS 17-20 with FIGS. 17 and 18 showing the static U-shape “prior to” application, FIGS. 18 and 20 showing the static U-shape “subsequent to” application, and FIGS. 17-20 showing the static U-shape throughout application.

The “retainers 320, 322 .. preferably are of a length at least  $\Pi$  times the distance between the arms 312, 314.” *Id.*, page 25, lines 21-22. “From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener.” *Id.*, page 25, lines 21-22.

## **B. Independent Claim 17**

Independent claim 17 recites:

*A kit, comprising:*

- a) at least one surgical clip; and*
- b) an applier for applying said at least one surgical clip to tissue, wherein*

*said at least one surgical clip comprises a first arm, a second arm substantially parallel to said first arm, a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application, and at least one*

*deformable retainer extending from one of said arms, wherein said retainer has a length of at least approximately  $\Pi$  times the distance between the arms when the arms are substantially parallel.*

As described in the specification of the instant application, the inventive kit includes at least one surgical clip 310, shown in FIGS. 19 and 20, which includes “two arms 312, 314 connected by a bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Application as originally filed*, page 25, lines 5-8.

“[W]hen the clip 310 is pushed forward, the retainer 320 is bent by the groove inside the hook 46 and the retainer 322 is bent by the groove inside the hook 48 to the configuration shown in Figure 20.” *Id.*, page 25, lines 14-17. It is only the retainer portions 320 and 322 of the clip that deforms. *Compare* FIG. 19 to FIG. 20. Both before, during, and after the bending process, the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U shape. *Id.* This static U-shape is shown in FIGS 17-20 with FIGS. 17 and 18 showing the static U-shape “prior to” application, FIGS. 18 and 20 showing the static U-shape “subsequent to” application, and FIGS. 17-20 showing the static U-shape throughout application.

The “retainers 320, 322 .. preferably are of a length at least  $\Pi$  times the distance between the arms 312, 314.” *Id.*, page 25, lines 21-22. “From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener.” *Id.*, page 25, lines 21-22.

FIG. 1 shows a clip applicator 10 that “generally includes a flexible wound outer coil 12 having a proximal end 14 and a distal end 16.” *Id.*, page 15, lines 3-5.

### **C. Independent Claim 21**

Independent claim 21 recites:

*A surgical clip, comprising:*

*a first arm;*

*a second arm substantially parallel to said first arm;*

*a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second arms being substantially parallel to one another prior to, throughout, and subsequent to application;*

*at least one deformable retainer extending from one end of said arms in a direction, said retainer having a length in said direction equal to a multiple of a distance between said arms, said multiple being greater than 2.5.*

As described in the specification of the instant application, the inventive kit includes at least one surgical clip 310, shown in FIGS. 19 and 20, which includes

“two arms 312, 314 connected by a bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Application as originally filed*, page 25, lines 5-8.

“[W]hen the clip 310 is pushed forward, the retainer 320 is bent by the groove inside the hook 46 and the retainer 322 is bent by the groove inside the hook 48 to the configuration shown in Figure 20.” *Id.*, page 25, lines 14-17. It is only the retainer portions 320 and 322 of the clip that deform. *Compare* FIG. 19 to FIG. 20. Both before, during, and after the bending process, the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U shape. *Id.* This static U-shape is clearly shown in FIGS 17-20 with FIGS. 17 and 18 showing the static U-shape “prior to” application, FIGS. 18 and 20 showing the static U-shape “subsequent to” application, and FIGS. 17-20 showing the static U-shape throughout application.

The “retainers 320, 322 .. preferably are of a length at least  $\Pi$  [(3.14)] times the distance between the arms 312, 314.” *Id.*, page 25, lines 21-22. “From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener.” *Id.*, page 25, lines 21-22.

#### **D. Independent Claim 22**

Independent claim 22 recites:

*A surgical clip, comprising:*

*a first arm;*

*a second arm substantially parallel to said first arm;*

*a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application; and*

*at least one deformable retainer extending from one of said arms and having a deformable portion, said deformable portion of said retainer having a length of at least approximately  $\Pi$  times the distance between said arms when said arms are substantially parallel.*

As described in the specification of the instant application, the inventive kit includes at least one surgical clip 310, shown in FIGS. 19 and 20, which includes “two arms 312, 314 connected by a bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Application as originally filed*, page 25, lines 5-8.

“[W]hen the clip 310 is pushed forward, the retainer 320 is bent by the groove inside the hook 46 and the retainer 322 is bent by the groove inside the hook 48 to the configuration shown in Figure 20.” *Id.*, page 25, lines 14-17. It is

only the retainer portions 320 and 322 of the clip that deforms. *Compare* FIG. 19 to FIG. 20. Both before, during, and after the bending process, the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U shape. *Id.* This static U-shape is shown in FIGS 17-20 with FIGS. 17 and 18 showing the static U-shape “prior to” application, FIGS. 18 and 20 showing the static U-shape “subsequent to” application, and FIGS. 17-20 showing the static U-shape throughout application.

The “retainers 320, 322 .. preferably are of a length at least  $\Pi$  times the distance between the arms 312, 314.” *Id.*, page 25, lines 21-22. “From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener.” *Id.*, page 25, lines 21-22.

#### **E. Independent Claim 32**

Independent claim 32 recites:

*A surgical clip, comprising:*

*a first arm;*

*a second arm substantially parallel to said first arm;*

*a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second arms being substantially parallel to one another and being physically separated from one another when substantially*

*parallel to one another prior to, throughout, and subsequent to application; and*

*at least one deformable retainer extending from one end of said arms in a direction, said retainer having a length in said direction equal to a multiple of a distance between said arms, said multiple being greater than 2.5.*

As described in the specification of the instant application, the inventive kit includes at least one surgical clip 310, shown in FIGS. 19 and 20, which includes “two arms 312, 314 connected by a bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Application as originally filed*, page 25, lines 5-8.

“[W]hen the clip 310 is pushed forward, the retainer 320 is bent by the groove inside the hook 46 and the retainer 322 is bent by the groove inside the hook 48 to the configuration shown in Figure 20.” *Id.*, page 25, lines 14-17. It is only the retainer portions 320 and 322 of the clip that deforms. *Compare* FIG. 19 to FIG. 20. Both before, during, and after the bending process, the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U shape. *Id.* This static U-shape is shown in FIGS 17-20 with FIGS. 17 and 18 showing the static U-shape “prior to” application, FIGS. 18 and 20 showing the static U-shape “subsequent to” application, and FIGS. 17-20 showing the static U-shape throughout application.

The “retainers 320, 322 .. preferably are of a length at least  $\Pi$  times the distance between the arms 312, 314.” *Id.*, page 25, lines 21-22. “From Figure 20, it will be appreciated that each retainer punctures the fundus twice substantially forming a circular fastener.” *Id.*, page 25, lines 21-22.

## **VII. ARGUMENT**

### **A. The Rejection of Claims 1, 2, 4, 17, 18, 21-23, 25 and 32 Under 35 U.S.C. § 102(b) is Improper Because Yoon does not anticipate the Presently-Claimed Invention**

Claims 1, 2, 4, 17, 18, 21-23, 25 and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated over Yoon. Appellants hereby appeal the Examiner’s Final rejection of claims 1, 2, 4, 17, 18, 21-23, 25 and 32 under 35 U.S.C. § 102(b) on the basis that the Examiner failed to meet the burden of showing that Yoon describes a surgical clip having a bridge that connects a first arm and a second arm to form a substantially static U-shaped structure and, particularly fails to show a U-shaped structure that is retained prior to, throughout and subsequent to application of the clip, each of which are required elements of each independent claim of the instant application (i.e., claims 1, 17, 21, 22 and 32). Accordingly, Yoon does not anticipate each and every element of the presently claimed invention and, therefore, the anticipation rejection should be withdrawn.

(i) Independent Claims 1, 17 and 22

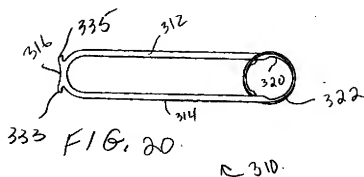
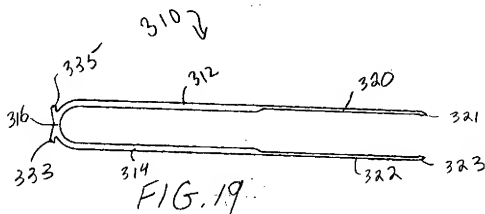
Claims 1, 17, and 22 recite, *inter alia*,

*a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application*

The present invention concerns a surgical clip inserted by a clip applier after the clip applier jaws grasp and puncture an invaginated fundus. *See, e.g.*, pages 19-21 of the application as originally filed. The tissue is plicated and the retainer arms are caused to slide over the tissue for a distance. *Id.* Then, only the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus. *See* FIG. 13 and element 22 in FIGS. 17 and 18 and elements 320 and 322 in FIGS. 19 and 20 of the instant application.

The claims provide that a property of the connecting bridge (316) is that its stiffness retains the two parallel arms (312, 314) in a “static” U-shaped form prior to, throughout, and subsequent to application. *Id.*, page 23 and FIGS 17-20. Merriam Websters’ dictionary defines static as: “standing or fixed in one place.” (Emphasis added). Because the shape of the presently invention surgical clip is “static,” the bridge does not just retain a U-shaped structure prior to, throughout, and subsequent to application; it retains substantially the same initial U-shaped structure prior to, throughout, and subsequent to application such that the shape

and diameter of the U-shape does not change at any time in any relevant way. This property is shown in, for instance, FIGS. 19 and 20 of the instant application (reproduced below for the Board's convenience.)



Only the deformable retainer (element 22 in FIGS. 17 and 18 and elements 320 and 322 in FIGS. 19 and 20) at the end of one or both of the arms is/are plastically deformable during and subsequent to application of the surgical clip. Compare FIG. 17 to FIG. 18 and FIG. 19 to FIG. 20. The elevational view of FIGS. 17 and 19 show that the material of the retainers is thinner than the material of the arms. This thinner material provides a structural ability for the arms to

remain stiff and fixed in the static U-shape, while the retainer deforms. This static, i.e., non-changing U-shape property of the arms and bridge is made abundantly clear in independent claims 1, 17, and 22 of the instant application.

#### Cited Art

Throughout prosecution of the instant application, the Examiner has identified a single embodiment of Yoon (Yoon's FIG. 10) as supposedly anticipating the claimed U-shaped structure of the instant application. Appellants do not deny that Yoon's FIG. 10 does show a U-shaped structure. However, Yoon's device is used entirely different than the surgical clip of the present invention and Yoon's U-shape is only present prior to application of the clip. As FIGS. 1-5 of Yoon (reproduced below for the Board's convenience) show, Yoon is designed to be compressed flat and the shape of Yoon's clip completely changes as it is applied to tissue (T). More specifically, as the specification of Yoon describes:

With clip 10 held between jaws 54 and 56 of the clip applier, anatomical tissue T, such as a tubular vessel or organ, is positioned within the tissue receiving space between arms 16 and 18, and the jaws 54 and 56 are closed together. Distal end 27 of upper arm 16 approaches hook 23 of lower arm 18 and mates with the hook to form a closed loop surrounding the tissue T as shown in FIG. 3. Further compression of the clip 10 causes staple legs 50 to penetrate through the anatomical tissue T and to be received within apertures 36 in upper arm 16 as shown in FIG. 4. The sharp tissue penetrating tips of the staple legs 50 protrude from the apertures 36 and are bent against the upper jaw 54 to engage the outer face 38 of upper arm 16

as shown in FIG. 5. The legs 50 will remain in the bent condition as a result of their being plastically shaped or deformed and will thus hold the arms of the clip together while applying a uniform pressure 15 across the occluded tissue. With the staple legs 50 properly formed, jaws 54 and 56 can be opened and moved away from the tissue T leaving the clip 10 securely clamped around the tissue T as shown in FIG. 6.

(Emphasis added)

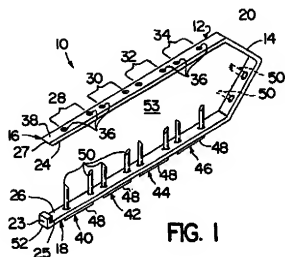


FIG. 1

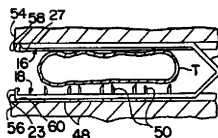


FIG. 2

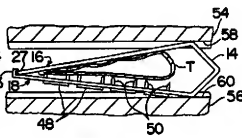


FIG. 3

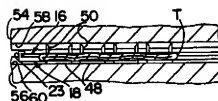


FIG. 4

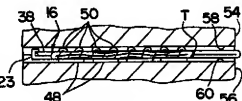


FIG. 5

Clearly, Yoon's FIG. 5 (subsequent to application) has a different shape than Yoon's FIG. 1 (prior to application). Yoon states, about its embodiment shown in FIG. 10, that:

The modified surgical clip shown in FIG. 10 is similar to those previously described but with a rounded or semicircular base 14 and staples 40 mounted on both the upper and lower arms 16 and 18 with tissue penetrating legs 50 positioned opposite apertures 36 formed in the other arm. When applied to anatomical tissue in the manner described above, the clip shown in FIG. 10 will have plastically shaped or deformed legs ....

(Emphasis added)

By using this language, Yoon expressly states that it does not have a "substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application," as is recited by independent claims 1, 17, and 22 of the instant application. In addition, Yoon's figures clearly show that its clips are substantially deformed during and after application.

For a rejection to be proper under 35 U.S.C. § 102(b), a single reference must teach (i.e., identically describe) each and every element of the rejected claims.<sup>1</sup> Because the elements in independent claims 1, 17, and 22 of the instant application are not taught or disclosed by Yoon, the apparatus of Yoon does not anticipate the present invention. The Appellants respectfully submit that the

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<sup>1</sup> See MPEP §2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.") (emphasis added); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim.").

Examiner's rejection under 35 U.S.C. § 102(b) has been overcome and should be removed.

In addition, Appellants previously set forth these and/or similar arguments in their July 7, 2009 response to the May 7, 2009 Final Office Action. In the Examiner's October 19, 2009 Advisory action, the Examiner refused to enter further amendments and, instead of identifying how Yoon shows the claimed features of the present invention, the Examiner continued the rejection of claims 1, 17, and 22. To justify the continued rejection, the Examiner stated that "the 'bridge connecting said first and second arms ... retain the same initial shape prior to, throughout and subsequent to application' changes the scope of the claimed invention and would require further consideration and an updated search." Confusingly, however, the language "a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application" has been in the claims since the July 30, 2008 Preliminary Amendment. Therefore, the Examiner's October 22, 2008 Office Action and the May 7, 2009 Final Office Action were both issued after a necessary examination of this language. The Examiner's conclusion that the scope of the search has changed is clearly erroneous and must be reversed.

(ii) Independent Claim 21

Claim 21 recites, *inter alia*,

*a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second arms being substantially parallel to one another prior to, throughout, and subsequent to application;*

The arguments set forth above in the section entitled “(i) Independent Claims 1, 17 and 22,” are equally applicable with respect to claim 21. As such, the arguments above are incorporated herein by reference in their entirety and are not repeated for the sake of brevity.

Yoon does not disclose each and every one of the features of claim 21, namely, a “substantially static U-shaped structure with said first and second arms being substantially parallel to one another prior to, throughout, and subsequent to application.” Specifically, Yoon’s FIG. 3 shows the arms in a non-parallel orientation “throughout” application to tissue. Accordingly, Yoon does not anticipate claim 21.

(iii) Independent Claim 32

Claim 32 recites, *inter alia*,

*a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second*

*arms being substantially parallel to one another and being physically separated from one another when substantially parallel to one another prior to, throughout, and subsequent to application*

The arguments set forth above in the section entitled “(i) Independent Claims 1, 17 and 22,” are equally applicable with respect to claim 32. As such, the arguments above are incorporated herein by reference in their entirety and are not repeated for the sake of brevity.

Claim 32 also describes the arms being substantially parallel to one another and being physically separated from one another when substantially parallel to one another prior to, throughout, and subsequent to application. This feature can be seen in FIGS. 17-20 of the instant application.

Yoon, in contrast, as can be seen in Yoon’s FIG. 3, has arms that are in a non-parallel orientation “throughout” application to tissue. As further shown in FIGS. 4 and 5 of Yoon, between what is labeled as elements 58 and 60, Yoon compresses its clip so that portions of the arms are in direct contact with one another. Therefore, Yoon does not disclose a clip with each and every one of the features of claim 32, namely, a “a substantially static U-shaped structure with said first and second arms being substantially parallel to one another and being physically separated from one another when substantially parallel to one another

prior to, throughout, and subsequent to application.” Accordingly, Yoon does not anticipate claim 32.

(iv) Dependent Claims 2, 4, 18, 23, and 25

Claims 2 and 4 depend from claim 1. Claim 18 depends from claim 17. Claims 23 and 25 depend from claim 22. Rejected dependent claims 2 and 4 stand or fall with independent claim 1. Rejected dependent claim 18 stands or falls with independent claim 17. Rejected dependent claims 23 and 25 stand or fall with independent claim 22.

**B. The Rejection of Claims 3, 7, 24, and 28 Under 35 U.S.C. § 103(a) is Improper Because Yoon in View of Nakao Does Not Derive the Presently-Claimed Invention**

Claims 3, 7, 24, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoon in view of Nakao. Claims 3 and 7 depend from claim 1. Claims 24 and 28 depend from claim 22.

Rejected dependent claims 3 & 7 and 24 & 28 stand or fall with independent claims 1 and 22, respectively.

**C. The Rejection of Claims 5, 6, 8-10, 26, 27, and 29-31 Under 35 U.S.C. § 103(a) is Improper Because Yoon in View of Nakao and further in view of Barrows Does Not Derive the Presently-Claimed Invention**

Claims 5, 6, 8-10, 26, 27, and 29-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoon in view of Nakao and further in view of Barrows.

Claims 5, 6, and 8-10 depend from claim 1. Claims 26, 27, and 29-31 depend from claim 22.

Rejected dependent claims 5, 6, and 8-10 stand or fall with independent claim 1. Rejected dependent claims 26, 27, & 29-31 stand or fall with independent claim 22.

#### **D. Conclusion**

In view of the remarks and arguments given above, Yoon fails to anticipate the presently claimed invention. Accordingly, claims 1, 2, 4, 17, 18, 21-23, 25, and 32 are allowable and the Examiner's rejections under 35 U.S.C. § 102(b) have been overcome and should be withdrawn.

In view of the remarks and arguments given above, the combination of Yoon and Nakao fails to teach or suggest the presently claimed invention. Accordingly, claims 3, 7, 24, and 28 are allowable and the Examiner's rejections under 35 U.S.C. § 103(a) have been overcome and should be withdrawn.

In view of the remarks and arguments given above, the combination of Yoon, Nakao, and Barrows fails to teach or suggest the presently claimed invention. Accordingly, claims 5, 6, 8-10, 26, 27, and 29-31 are allowable and the Examiner's rejections under 35 U.S.C. § 103(a) have been overcome and should be withdrawn.

Appellants hereby respectfully request reconsideration and allowance of pending claims 1 to 10, 17 to 18, and 21 to 32 of the instant application.

Dated: November 19, 2009

Respectfully submitted,

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## **VIII. CLAIMS APPENDIX**

1 (previously amended). A surgical clip, comprising:

- a) a first arm;
- b) a second arm substantially parallel to said first arm;
- c) a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application;
- d) at least one deformable retainer extending from one end of said arms in a direction, wherein  
  
said retainer has a length in said direction of at least approximately  $\Pi$  times the distance between the arms when the arms are substantially parallel.

2 (original). A surgical clip according to claim 1, wherein:

said first arm has a first thickness and said retainer has a second thickness smaller than said first thickness.

3 (previously amended). A surgical clip according to claim 1, wherein:

said at least one deformable retainer is a pair of deformable retainers, one extending from each of said first and second arms, both retainers having a sharp tip and both retainers being approximately the same length.

4 (original). A surgical clip according to claim 1, wherein:

said retainer has a sharp tip.

5 (original). A surgical clip according to claim 1, wherein:

said retainer is decouplable from said one of said arms.

6 (original). A surgical clip according to claim 5, wherein:

said retainer is removably coupled to said arms by a friction fit.

7 (previously amended). A surgical clip according to claim 2, wherein:

said at least one deformable retainer is a pair of deformable retainers, one extending from each of said first and second arms, both retainers having a sharp tip and both retainers being approximately the same length.

8 (previously amended). A surgical clip according to claim 7, wherein:

each of said retainers is decouplable from said arms.

9 (previously amended). A surgical clip according to claim 8, wherein:

each of said retainers is removably coupled to said arms by friction fits.

10 (original). A surgical clip according to claim 9, wherein:

each of said arms includes an end portion defining a slot, and each of said deformable retainers includes a proximal portion which has a friction fit with a respective slot.

11 to 16 (canceled)

17 (previously amended). A kit, comprising:

- a) at least one surgical clip; and
- b) an applicator for applying said at least one surgical clip to tissue, wherein

said at least one surgical clip comprises a first arm, a second arm substantially parallel to said first arm, a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application, and at least one deformable retainer extending from one of said arms, wherein said retainer has a length of at least approximately  $\Pi$  times the distance between the arms when the arms are substantially parallel.

18 (previously amended). A kit according to claim 17, wherein:

said at least one surgical clip is a plurality of surgical clips.

19 to 20 (canceled)

21 (previously amended). A surgical clip, comprising:

a first arm;

a second arm substantially parallel to said first arm;

a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second arms being substantially parallel to one another prior to, throughout, and subsequent to application;

at least one deformable retainer extending from one end of said arms in a direction, said retainer having a length in said direction equal to a multiple of a distance between said arms, said multiple being greater than 2.5.

22 (previously amended). A surgical clip, comprising:

a first arm;

a second arm substantially parallel to said first arm;

a bridge connecting said first and second arms to form a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application; and

at least one deformable retainer extending from one of said arms and having a deformable portion, said deformable portion of said retainer having a length of at least approximately  $\Pi$  times the distance between said arms when said arms are substantially parallel.

23 (original). A surgical clip according to claim 22, wherein said first arm has a first thickness and said retainer has a second thickness smaller than said first thickness.

24 (previously amended). A surgical clip according to claim 22, wherein said retainer is a pair of deformable retainers, one extending from each of said first and second arms, both retainers having a sharp tip and both retainers being approximately the same length.

25 (original). A surgical clip according to claim 22, wherein said retainer has a sharp tip.

26 (original). A surgical clip according to claim 22, wherein said retainer is decouplable from said one of said arms.

27 (original). A surgical clip according to 26, wherein said retainer is removably coupled to said arms by a friction fit.

28 (previously amended). A surgical clip according to claim 23, wherein said deformable retainer is a pair of deformable retainers, one extending from each of said first and second arms, both retainers having a sharp tip and both retainers being approximately the same length.

29 (previously amended). A surgical clip according to claim 28, wherein each of said retainers is decouplable from said arms.

30 (previously amended). A surgical clip according to claim 29, wherein each of said retainers is removably coupled to said arms by friction fits.

31 (original). A surgical clip according to claim 30, wherein each of said arms includes an end portion defining a slot, and each of said deformable retainers includes a proximal portion having a friction fit with respective slot.

32 (previously amended). A surgical clip, comprising:

a first arm;

a second arm substantially parallel to said first arm;

a bridge connecting said first and second arms to form a substantially static U-shaped structure with said first and second arms being substantially parallel to one another and being physically separated from one another when substantially parallel to one another prior to, throughout, and subsequent to application; and

at least one deformable retainer extending from one end of said arms in a direction, said retainer having a length in said direction equal to a multiple of a distance between said arms, said multiple being greater than 2.5.

## **IX. EVIDENCE APPENDIX**

No additional evidence has been submitted with this brief.

## **X. RELATED PROCEEDINGS APPENDIX**

There are no related proceedings.